PEARSON, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

KATHLEEN BARRECA, Plaintiff, v. ANGIODYNAMICS, INC., et al., Defendants.	)))))))))	CASE NO. 4:15CV1111 JUDGE BENITA Y. PEARSON **MEMORANDUM OF OPINION AND ORDER** [Resolving ECF No. 9]

Pending is Defendant AngioDynamics, Inc.'s Motion to Dismiss First Amended Complaint (ECF No. 9) with prejudice pursuant to Fed. R. Civ. P. 12(b)(6) for failure to meet the requisite *Twombly*/*Iqbal* pleading standards because it fails to set forth sufficient factual support for Plaintiff Kathleen Barreca's claims. The Court has been advised, having reviewed the record, the parties' briefs and the applicable law. The Court has also considered the statements of counsel offered at the August 26, 2015 Case Management Conference ("CMC"). For the reasons set forth below, the Court denies the motion.

I. Background

On or about January 1, 2011, Plaintiff went to the hospital to have a Mediport surgically implanted into her subclavicular area. First Amended Complaint (ECF No. 5) at PageID #: 49, ¶ 10. The Mediport, "believed to be manufactured by [AngioDynamics],"[1] was surgically implanted into Plaintiff's subclavicular area for the purpose of subcutaneously administering

[1] AngioDynamics is in the business of designing, manufacturing and selling medical devices. ECF No. 5 at PageID #: 48, ¶ 2.

medications to Plaintiff. ECF No. 5 at PageID #: 49, ¶¶ 11 and 12.[2] Plaintiff received an injection into the Mediport from a home health care nurse on a monthly basis for the purpose of administering medication or flushing the Mediport with a saline solution. ECF No. 5 at PageID #: 49, ¶¶ 13 and 14.

On April 22, 2013, a nurse came to Plaintiff's home to flush the Mediport. ECF No. 5 at PageID #: 49-50, ¶ 15. While the Mediport was being flushed, Plaintiff began to experience severe chest pain and the nurse observed a pinkish fluid coming from the Mediport. ECF No. 5 at PageID #: 50, ¶ 16. The nurse immediately ceased flushing the Mediport and observed that a large subcutaneous mass had developed near the Mediport. ECF No. 5 at PageID #: 50, ¶ 17. Plaintiff immediately went to the hospital to seek treatment for her symptoms. ECF No. 5 at PageID #: 50, ¶ 18. A portable chest x-ray revealed that the catheter had detached from the Mediport with frayed ends to both the catheter and port. Evidence of frayed tubing was seen in Plaintiff's right atrium. The catheter portion of the Mediport released from its housing in the right ventricle. ECF No. 5 at PageID #: 50, ¶ 19 and 20.[3]

On or about April 24, 2013, Plaintiff was admitted to the hospital to have surgery to extract the Mediport. ECF No. 5 at PageID #: 50, ¶ 21. Plaintiff remained in the Intensive Care

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[2] In general, a subclavian port is a small device containing a thin catheter that is implanted under the skin and used to administer drugs and nutrients. Such ports are typically used for patients in need of frequent intravenous treatments. ECF No. 9-1 at PageID #: 90 n.2. *See, e.g.*, *Izquierdo-Garcia v. AngioDynamics, Inc.*, No. 3:12-cv-01175-JAG-BJM (D. Puerto Rico filed March 12, 2012).

[3] Paragraph 19 contains a typographical error. The Court was informed at the CMC that Plaintiff had a portable chest x-ray on April 22, 2013, not 2014.

Unit for a few days to monitor her condition following the Mediport extraction, then she was discharged. ECF No. 5 at PageID #: 50, ¶ 22.

On or about April 27, 2013, Plaintiff was readmitted to the hospital for pneumonia. After one week, Plaintiff was released to a rehabilitation facility where she remained until June 6, 2013. ECF No. 5 at PageID #: 50, ¶ 23 and 24.

On April 22, 2015, Plaintiff, an individual residing in Trumbull County, Ohio (ECF No. 5 at ¶ 1), filed a Complaint (ECF No. 1-1 at PageID #: 9-23) alleging product liability causes of action against AngioDynamics in the Mahoning County, Ohio Court of Common Pleas, being Case No. 2015 CV 01086. AngioDynamics removed the case to this Court on June 2, 2015, on the basis of diversity of citizenship jurisdiction. AngioDynamics is a Delaware corporation with its principal place of business in Latham, New York. Notice of Removal (ECF No. 1) at PageID #: 2, ¶ 10; ECF No. 5 at PageID #: 48, ¶ 2.

On June 27, 2015, Plaintiff filed an eight-count First Amended Complaint (ECF No 5) against AngioDynamics and John/Jane Does Nos. 1-10. It asserts four (4) claims under the Ohio Product Liability Act, Ohio Rev. Code § 2307.71, *et seq.* (the "OPLA") against AngioDynamics: (1) defective manufacture or construction; (2) defective design or formulation; (3) inadequate warning and/or instruction; and, (4) nonconformance with manufacturer's representations.[4]

[4] Plaintiff also asserts the same corresponding four claims against defendants John/Jane Does Nos. 1-10 in the Second, Fourth, Sixth, and Eighth Claims of the First Amended Complaint (ECF No 5). Counsel for Plaintiff stated during the CMC that Plaintiff will not be pursuing these claims because he believes AngioDynamics is the manufacturer of Mediport that was surgically implanted into Plaintiff.

II. Standard of Review

In deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the Court must take all well-pleaded allegations in the complaint as true and construe those allegations in a light most favorable to the plaintiff. *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (citations omitted). A cause of action fails to state a claim upon which relief may be granted when it lacks "plausibility in th[e] complaint." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 564 (2007). A pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." *Ashcroft v. Iqbal* , 556 U.S. 662, 677-78 (2009) (quoting Fed. R. Civ. P. 8(a)(2)). Plaintiff is not required to include detailed factual allegations, but must provide more than "an unadorned, the-defendant-unlawfully-harmed-me accusation." *Id.* at 678. A pleading that offers "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Nor does a complaint suffice if it tenders "naked assertion[s]" devoid of "further factual enhancement." *Id.* at 557. It must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Twombly*, 550 U.S. at 556. Where a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* at 557 (brackets omitted).

III. Analysis

A. The First Amended Complaint (ECF No. 5) Properly Identifies Alleged Defective Manufacturing of the Mediport and Catheter.

AngioDynamics argues that the First Claim for strict product liability for defective manufacturing under Ohio Rev. Code § 2307.74 (ECF No. 5 at PageID #: 50-52, ¶¶ 25-35) does not identify any manufacturing defect in the Mediport and catheter. Section 2307.74 provides:

> A product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards. A product may be defective in manufacture or construction as described in this section even though its manufacturer exercised all possible care in its manufacture or construction.

The allegations in the First Claim are sufficient to state a claim for relief for defective manufacturing. At a minimum, courts have required allegations that the defendant manufactured the product, that the product was used by the plaintiff, that the product failed while being used by the plaintiff, and that the portion of the product that failed could be identified and is so identified in the complaint. *See, e.g.*, *Marcum v. DePuy Orthopedics, Inc.*, No.: 1:12-cv-834, 2013 WL 1867010, at *5 (S.D. Ohio May 2, 2013) (holding that allegations that plaintiff had defendant's hip replacement parts surgically implanted, the hip replacement parts broke while implanted, that defendant's products can be identified, and that defendant was required to maintain good manufacturing practices were sufficient to allege claims for manufacturing and design defect). Plaintiff has done this in the case at bar.

B. The First Amended Complaint (ECF No. 5) Properly Identifies Alleged Defective Design of the Mediport and Catheter.

The Third Claim is for strict product liability for defective design under Ohio Rev. Code § 2307.75. ECF No. 5 at PageID #: 53-54, ¶¶ 47-55. AngioDynamics argues that this claim fails because it does not identify any design defect in the Mediport and catheter. Section 2307.75(A) provides, in pertinent part: ". . . a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation . . . . Section 2307.75(B)-(C) sets forth factors to be considered in balancing the foreseeable risks and the benefits associated with the design or formulation.

The allegations in the Third Claim are sufficient to state a claim for relief for defective design. The First Amended Complaint (ECF No. 5) alleges that AngioDynamics designed the Mediport (ECF No. 5 at PageID #: 48, ¶ 2 and PageID #: 49, ¶ 12); Plaintiff used the Mediport to receive medications into her subclavicular area (ECF No. 5 at PageID #: 49, ¶ 13); the Mediport failed while it was being used by Plaintiff (ECF No. 5 at PageID #: 50, ¶ 16); and, the portion of the product that failed is identified in the pleading as the frayed ends to both the catheter and port after the catheter detached from the Mediport (ECF No. 5 at PageID #: 50, ¶ 20). *Marcum*, 2013 WL 1867010, at *5. This claim survives dismissal.

C. Plaintiff's Claim for Defect Due to Inadequate Warning is Sufficiently Pled.

Next, AngioDynamics argues that the Fifth Claim for failure to adequately warn of the Mediport's risks (ECF No. 5 at PageID #: 56-57, ¶¶ 65-72) does not identify any warning or any deficiency in any warning. Plaintiff's claim for inadequate warning is based on Ohio Rev. Code

§ 2307.76(A). This statute provides that a product is defective due to inadequate warning or instruction at the time of marketing if, when it left the manufacturer's control, the manufacturer (1) knew or should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages and (2) failed to provide the warning or instruction a manufacturer exercising reasonable care would have provided concerning that risk. § 2307.76(A)(1). It also provides a claim for inadequate post-marketing warning which provides that a product is defective due to inadequate post-marketing warning if, at a relevant time after it left the control of its manufacturer, the manufacturer (1) knew or should have known about a risk that is associated with the product and that allegedly caused harm for which the claimant seeks to recover compensatory damages and (2) failed to provide the post-marketing warning or instruction that a manufacturer exercising reasonable care would have provided concerning that risk. § 2307.76(A)(2).

Defendant's argument that Plaintiff's inadequate warning and/or instruction claim is inadequately pled lacks merit. Plaintiff has pled sufficient facts to support a plausible inference that AngioDynamics failed to adequately warn of its Mediport's risks. The First Amended Complaint (ECF No. 5) alleges that the Mediport catheter frayed during normal use and, as a result, fragments from the catheter and port entered Plaintiff's right atrium requiring surgical removal of the Mediport. ECF No. 5 at PageID #: 50, ¶¶ 16-21. It also alleges that AngioDynamics (1) knew of the risks associated with the Mediport; (2) failed to provide sufficient warnings and/or instructions that a similarly situated manufacturer would have provided concerning the risks; and, (3) that those warnings were not provided to Plaintiff or her

implanting physician. ECF No. 5 at PageID #: 56-57, ¶¶ 68-70. In *Liming v. Stryker Corp.*, No. 1:11-CV-00788, 2012 WL 1957287 (S.D. Ohio May 31, 2012), the complaint set forth allegations that Defendants knew or should have known that the pain pump created significant risks of chondrolysis when used in the shoulder joint and that they failed to adequately warn Plaintiff or Plaintiff's physician of those risks. The court found "[a]t this stage, for this claim, that is sufficient." *Id.* at *5. The same is true in this case.

D. Plaintiff's Claim for Defect Due to Nonconformance With Representations is Sufficiently Pled.

The Seventh Claim is that AngioDynamics is liable for nonconformance with its representations about the Mediport and catheter under Ohio Revised Code § 2307.77. ECF No. 5 at PageID #: 58-59, ¶¶ 81-85. Section 2307.77, which codifies the common law claim of breach of express warranty, provides:

> A product is defective if it did not conform, when it left the control of its manufacturer, to a representation made by that manufacturer. A product may be defective because it did not conform to a representation even though its manufacturer did not act fraudulently, recklessly, or negligently in making the representation.

A plaintiff seeking to recover under this statute must show: (1) that the manufacturer made a representation as to a material fact concerning the character or quality of the manufacturer's product; (2) that the product did not conform to that representation; (3) that the plaintiff justifiably relied on that representation; and (4) that the plaintiff's reliance on the representation was the direct and proximate cause of the plaintiff's injuries. *Cervelli v. Thompson/Center Arms*, 183 F. Supp.2d 1032, 1045 (S.D. Ohio 2002) (quoting *White v. DePuy, Inc.*, 129 Ohio App.3d 472, 484-85 (1998)).

AngioDynamics argues that the Seventh Claim does not identify any representations. But, ¶ 83 of the First Amended Complaint (ECF No. 5) states, in pertinent part, the alleged representations included "representations to Plaintiff that the product was safe and fit for the particular purpose to which Plaintiff, Kathleen Barreca, would use the product." In this case, this allegation just barely clears the hurdle posed by Fed. R. Civ. P. 8(a)(2) that a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." *Contra* *Harris v. Eli Lilly & Co.*, No. 4:12CV2481, 2012 WL 6732725, at *4 (N.D. Ohio Dec. 28, 2012) (Adams, J.) (statement that drug was safe for use when it was in fact not cannot support a valid failure to conform claim). At the summary judgment stage, however, Plaintiff will have to present evidence sufficient to enable a reasonable trier of fact to conclude that the Mediport and catheter are defective because the product failed to conform to AngioDynamics' representation. *See* *Saraney v. TAP Pharmaceutical Products, Inc.*, No. 1:04CV02026, 2007 WL 148845, at *8 (N.D. Ohio Jan. 16, 2007) (Wells, J.) (summary judgment entered on plaintiffs' failure to conform claim when beyond a bare allegation in the complaint that defendant generally warranted the drug of "good, safe and merchantable quality," plaintiffs submitted no evidence of an express representation.).

IV. Conclusion

Because Plaintiff has pled sufficient facts pursuant to Fed. R. Civ. P. 8(a)(2) to state a claim for (1) defective manufacture or construction, (2) defective design or formulation,

(3) inadequate warning and/or instruction, and (4) nonconformance with manufacturer's representations, Defendant AngioDynamics, Inc.'s Motion to Dismiss First Amended Complaint (ECF No. 9) is denied.

IT IS SO ORDERED.

August 27, 2015
Date

/s/ Benita Y. Pearson
Benita Y. Pearson
United States District Judge